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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,415	07/29/2003	Ludger Johannes	2121-0176P	6282

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EXAMINER	
MINNIFIELD, NITA M	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/628,415	JOHANNES ET AL.	
	Examiner	Art Unit	
	N. M. Minnifield	1645	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *9-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *9-24* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892) 7 sheets

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/29/03*. 1 sheet

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 1-8, in the reply filed on November 4, 2004 is acknowledged. The traversal is on the grounds that the Examiner should examine the inventions of Group III and Group IV together with the invention of elected Group the same time. For example, each of these Groups utilizes a common technical feature, that is, the polypeptidic carrier of claim 1. Specifically, the composition of Group IV utilizes the polypeptidic carrier of claim 1, as does the method of Group III. Moreover, the method claims of Group III should at the very least be rejoined in accordance with MPEP 821.04. Finally, the Examiner has not established that there is an undue burden in considering Groups I, III and IV at the same time. Accordingly, the Examiner should withdraw the requirement for restriction.

This is not found persuasive. The Examiner would like to bring to Applicants' attention that the pending application is a National Stage of a PCT application (PCT/EP02/01627) and as such Restriction is required under 35 USC 121 and 372. As previously stated in the Restriction Requirement mailed October 4, 2004, the inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The technical feature of Group I, the universal polypeptidic carrier comprising the Shiga Toxin B, amino acid or polypeptide and cysteine is not special in view of the carrier being disclosed in Haicheur et al (J. Immunology, 2000, 265:3301-3308). The technical feature of Group I is not special in that it does not define a novel contribution over the prior art, as such there is not a special technical feature and

therefore the Groups of inventions, I-IV, lack a corresponding special technical feature. The claimed invention does not have a technical feature that defines over the prior art.

It is noted that methods claims (i.e. Group III) will be rejoined if the product claims of Group I are deemed allowable as per MPEP 821.04.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 9-24 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention(s), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on November 4, 2004.

3. The disclosure is objected to because of the following informalities: there are letters missing from words through out the specification, see for example p. 6, l. 28, p. 15, l. 31 and p.16, l. 31. Applicants should review the entire specification and make corrections where necessary. Appropriate correction is required.

4. The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure for the claimed invention. The specification, at p. 8, lines 11-14, sets forth a plasmid pSU108 having SEQ ID No. 2 integrated between the SphI and SalI restriction sites, and the corresponding cell line has been deposited at CNCM on December 19, 2000 with the registration number 1-2604. It appears that this plasmid is necessary to practice the claimed invention. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is

not so obtainable or available, a deposit of the above plasmid may satisfy the enablement requirements of 35 U.S.C. § 112, first paragraph. See 37 C.F.R. 1.802.

It is noted that the plasmid has been deposited. However, the certificate of deposit has not been provided nor have the statements of assurance been made, see below. If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. 1.808.

If the deposits have not been made under the provisions of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository (with address) and that the following criteria have been met:

(a) during the tendency of the application, access to the deposits will be afforded to one determined by the Commissioner to be entitled thereto;
(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;
© the deposits will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a

sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

5. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons set forth in the above objection to the specification.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Haicheur et al 2000 (J. Immunology, 2000, 165:3301-3308) or Lee et al 1998 (Eur. J. Immunol., 1998, 28:2726-2737) in light of Wang et al (WO 95/11998).

Haicheur et al discloses a construct of the B subunit of Shiga toxin fused to a

tumor peptide (abstract). The prior art discloses that the Shiga B subunit acts as a vector (i.e. carrier) (see abstract; p. 3301, col. 2). Haicheur et al discloses that the "Shiga B subunit targets this pathway in a receptor-dependent manner, namely via binding to the glycolipid Gb3. Because this receptor is highly expressed on various dendritic cells, it should allow preferential targeting of the Shiga B subunit to these professional APCs. Therefore, the Shiga B subunit appears to represent an attractive vector for vaccine development due to its ability to target dendritic cells and to induce specific CTL without the need for adjuvant." (abstract) Haicheur et al discloses different peptides and proteins (i.e. OVA, SL8, P815A and P1A) can be fused to the Shiga B subunit (materials and methods, p. 3302, col. 1). It is well known in the art to add cysteine residues to synthetic peptides for polymerization. This is evidenced by Wang et al that discloses cysteine residues can be added to the N-terminus or the C-terminus to synthetic peptides to increase solubility and facilitate binding of the peptide to a carrier (p. 20; p. 23).

Lee et al discloses the fusion of Shiga B subunit and a tumor antigen, Mage 1 (abstract). Lee et al discloses the Shiga B subunit has the ability to target dendritic cells and B cells and to direct antigen into the exogenous class I-restricted pathway making it an attractive non-living and non-toxic vaccine vector (abstract; p. 2733). It is well known in the art to add cysteine residues to synthetic peptides for polymerization. This is evidenced by Wang et al that discloses cysteine residues can be added to the N-terminus or the C-terminus to synthetic peptides to increase solubility and facilitate binding of the peptide to a carrier (p. 20; p. 23).

Since the Patent Office does not have the facilities for examining and comparing applicants' carrier with the carrier of the prior art reference, the burden is upon applicants to show a distinction between the material structural and

functional characteristics of the claimed carrier and the carrier of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM

January 24, 2005